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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,895	03/20/2006	Yukiyo Sekimoto	SAEG125.003APC	1331

20995 7590 11/18/2008

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EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
11/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/572,895	SEKIMOTO ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,12,13,17 and 18* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 12, 13, 17, 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-6, 12, 13 in the reply filed on 12/4/2007 is acknowledged.

Claims 7 and 8 remain withdrawn from further consideration as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 12, 13, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Lovett (US 6881419).

Lovett teaches that Vitamin D3, calcium and soy isoflavones (which inherently contain compounds such as genistein and daidzein) are in the same composition, see table 1.

It is inherent that the same amount of genistein and daidzein are used as in the claims since such compounds are inherently found in soy. Note that about 27 % of calcium is used in the composition, 2.6×10^{-4} % of Vitamin D^3 and about 2.4 % of soy

isoflavones are used in the composition (when calculated with respect to the total composition).

Applicant argues that Lovett allegedly does not teach the claimed ratios of isoflavones. This is not agreed with since as shown by USDA-Iowa State University Database (USDA) soy fiber has 18.8 daidzein, 21.68 genistein and a total isoflavone content of 44.43 (see under "NDB No" 99045) meaning that the daidzein and the genistein are already in a ratio of 1.15 inherently and that 91 % is the total weight of genistein and daidzein inherently (for total isoflavone content) in the soy. Thus, the soy isoflavones taught by Lovett meet the claim limitations inherently since USDA shows what the soy isoflavones inherently contain. USDA shows the isoflavone content of foods from 1999 thus it shows what the soy fiber naturally contains which is what Lovett inherently shows.

Applicant alleges that the amount of soy isoflavones in USDA is 83.6 % and then gives absolutely no explanation of where such a calculation comes from. Further, as seen from the table in USDA as noted (at NDB No. 99045) it is clear as already noted on the record that the ratio of genistein/daidzein is met by the USDA reference since the ratio of 21.68/18.80 is 1:1.5 which clearly falls within the claimed ratio. The comments concerning the other references (Franke and Kudou) are not well taken because the USDA reference is very clear that the soy fiber will contain such ratios. Further, applicant argues that the same source of the soy isoflavone is not taught but the same

compounds (genistein and daidzein) are taught in the USDA reference which is what is being claimed. It does not matter where the compound comes from as long as the same compound is taught which clearly USDA is teaching namely, genistein and daidzein. It also does not matter that soy fiber is only one component of whole soybeans after all this is a plant extract. Further, as long as the claimed amounts are met, the compounds are taught by the references. Since the same ratio of genistein/daidzein is met by the USDA reference (since the ratio of 21.68/18.80 is 1:1.5), then it is submitted that the references cited clearly teach the claimed invention. Since USDA teaches that the natural soy fiber has the above characteristics then inherently the soy fiber has the claimed proportion of the total weight of genistein and daidzein in the soy isoflavone to be at least 90 %.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 12, 13, 17, 18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lovett (US 6881419).

Lovett teaches that Vitamin D3, calcium and soy isoflavones (which inherently contain compounds such as genistein and daidzein) are in the same composition, see table 1.

It is inherent that the same amount of genistein and daidzein are used as in the claims since such compounds are inherently found in soy. Note that about 27 % of calcium is used in the composition, 2.6×10^{-4} % of Vitamin D^3 and about 2.4 % of soy isoflavones are used in the composition (when calculated with respect to the total composition).

The cited reference teaches a composition containing the claimed components as noted above. The soy isoflavones in Lovett inherently contain the ratio of genistein/daidzein as claimed and contain genistein/daidzein at the claimed amounts since the claimed soy isoflavones of Lovett appear to be identical to (and thus anticipate) the presently claimed soy isoflavones since both contain soy isoflavones and both are from soy. Consequently, the instantly claimed composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed soy isoflavones are not identical to the referenced soy isoflavones with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced soy isoflavones are likely to inherently possess the same characteristics of the claimed soy isoflavones. Thus, the claimed soy isoflavones would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., extracting the soybean with known solvents to obtain an extract with the claimed amounts of genistein/daidzein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the claimed amounts of genistein/daidzein within Applicant's extracts differ and, if so, to what extent, from the levels within the soy isoflavone extract disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Applicant argues that Lovett allegedly does not teach the claimed ratios of isoflavones. This is not agreed with since as shown by USDA-Iowa State University Database (USDA) soy fiber has 18.8 daidzein, 21.68 genistein and a total isoflavone content of 44.43 (see under "NDB No" 99045) meaning that the daidzein and the genistein are already in a ratio of 1.15 inherently and that 91 % is the total weight of genistein and daidzein inherently in the soy. Thus, the soy isoflavones taught by Lovett meet the claim limitations inherently since USDA shows what the soy isoflavones inherently contain. USDA shows the isoflavone content of foods from 1999 thus it shows what the soy fiber naturally contains which is what Lovett inherently shows.

Applicant alleges that the amount of soy isoflavones in USDA is 83.6 % and then gives absolutely no explanation of where such a calculation comes from. Further, as

seen from the table in USDA as noted (at NDB No. 99045) it is clear as already noted on the record that the ratio of genistein/daidzein is met by the USDA reference since the ratio of 21.68/18.80 is 1:1.5 which clearly falls within the claimed ratio. The comments concerning the other references (Franke and Kudou) are not well taken because the USDA reference is very clear that the soy fiber will contain such ratios. Further, applicant argues that the same source of the soy isoflavone is not taught but the same compounds (genistein and daidzein) are taught in the USDA reference which is what is being claimed. It does not matter where the compound comes from as long as the same compound is taught which clearly USDA is teaching namely, genistein and daidzein. It also does not matter that soy fiber is only one component of whole soybeans after all this is a plant extract. Further, as long as the claimed amounts are met, the compounds are taught by the references. Since the same ratio of genistein/daidzein is met by the USDA reference (since the ratio of 21.68/18.80 is 1:1.5), then it is submitted that the references cited clearly teach the claimed invention. Since USDA teaches that the natural soy fiber has the above characteristics then inherently the soy fiber has the claimed proportion of the total weight of genistein and daidzein in the soy isoflavone to be at least 90 %.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655